

### Remarks/Arguments

In the Office Action, the Examiner imposed a new restriction requirement under 35 USC 121. While the Examiner addressed her comments to claims 12-53, Applicant respectfully notes that claims 12-54 were before the Examiner.

The Examiner has required a new restriction of the claims to one of the following inventions under 35 U.S.C. §121:

- I. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:1, classified in class 530, subclass 350.
- II. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:2, classified in class 530, subclass 350.
- III. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:3, classified in class 530, subclass 350.
- IV. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:4, classified in class 530, subclass 350.
- V. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:5, classified in class 530, subclass 350.
- VI. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:6, classified in class 530, subclass 350.
- VII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:7, classified in class 530, subclass 350.
- VIII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:8, classified in class 530, subclass 350.

- IX. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:9, classified in class 530, subclass 350.
- X. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:10, classified in class 530, subclass 350.
- XI. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:11, classified in class 530, subclass 350.
- XII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:12, classified in class 530, subclass 350.
- XIII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:13, classified in class 530, subclass 350.
- XIV. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein at least one polypeptide is SEQ ID NO:14, classified in class 530, subclass 350.
- XV. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:1, classified in class 424, subclass 234.1.
- XVI. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:2, classified in class 424, subclass 234.1.
- XVII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:3, classified in class 424, subclass 234.1.
- XVIII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:4, classified in class 424, subclass 234.1.
- XIX. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:5, classified in class 424, subclass 234.1.

- XX. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:6, classified in class 424, subclass 234.1.
- XXI. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:7, classified in class 424, subclass 234.1.
- XXII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:8, classified in class 424, subclass 234.1.
- XXIII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:9, classified in class 424, subclass 234.1.
- XXIV. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:10, classified in class 424, subclass 234.1.
- XXV. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:11, classified in class 424, subclass 234.1.
- XXVI. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:12, classified in class 424, subclass 234.1.
- XXVII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:13, classified in class 424, subclass 234.1.
- XXVIII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein at least one polypeptide is SEQ ID NO:14, classified in class 424, subclass 234.1.

The Examiner generally breaks down the claims into two groups as follows:

- Group I. Claims 12-32 (inventions I-XIV below), drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof, classified in class 530, subclass 350.
- Group II. Claims 33-53 (inventions XV-XXVIII below), drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof, classified in class 424, subclass 234.1.

The Examiner has required restriction between product and process claims. The Examiner indicates that the polypeptides of Group I may be used in materially different processes and therefore are distinct from the inventions in Group II. The Examiner contends that the compositions of Group I comprise products which are biologically, chemically and structurally different and are therefore patentably distinct and independent inventions. Furthermore, the Examiner indicates that the methods of Group II use immunogens which are biologically, chemically and structurally different. Therefore, the Examiner contends that methods of using these different compounds are patentably distinct and independent inventions.

The Examiner contends that the compositions represent different inventions and are not merely species of one another, e.g. a composition comprising SEQ ID NO:1, a composition comprising SEQ ID NO:1 and SEQ ID NO:14, a composition comprising SEQ ID NO:5, 8, and 13, etc. The Examiner therefore contends that all of the compositions would comprise completely different products and passes completely different immunogenic properties they would stimulate different immune responses.

The Examiner alleges that it would place a serious undue burden on the Examiner to examine all of the inventions together because they are distinct.

The Examiner states that Applicant must either elect a single polypeptide composition for examination of an invention in Group I, or a single polypeptide composition for use in the method for examination of an invention in Group II.

In response, Applicant has canceled pending claims 12-54 and submits new claims 55-89 of which Claims 55-71 are directed to compositions and claims 72-89 are directed to a method of eliciting an immune response in an animal, including a human, for treatment of the symptoms of psoriasis.

The Examiner's restriction requirement is rendered moot, since Applicant has canceled claims 1-54.

The Examiner previously required that Applicant elect either product or process claims. If the Examiner does not impose such a requirement on the new proposed claims, new claims 55-89 will be pending. In order to expedite prosecution, and in the event the Examiner imposes this requirement on the new claims, Applicant elects the composition claims, i.e., claims 55-71.

Support for new claims 55-71 may be found in the specification. For example, support for claims 55-58 may; be found, inter alia, on page 3, lines 18-24, support for claims 59 (the polypeptides in fraction 3), claim 60 (the polypeptides in fraction 4), 61 (fractions 3 and fraction 4), and 62-70 may be found in Table 18, and support for claim 71 may be found in page 14, lines 1-5.

The specification discloses that a composition comprising protein fractions 3 & 4 is formulated and administered intramuscularly. (Specification, page 16-17). Table 18 discloses that fractions 3 and 4, when totally reduced and alkylated, contains polypeptides having a

molecular weight of 73 kD, 80 kD, and 82 kD. (Specification, page 39-40). It further discloses that the 73 kD polypeptide in fraction 3 comprises peptides 10, 12, and 13, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 1, 5, and 6; that the 80 kD polypeptide in fraction 3 comprises peptide 10, peptide 13, and a 9 amino acid peptide, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 1, 3, and 4; and that the 82 kD polypeptide in fraction 3 comprise peptides 12 and 16, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 1 and 2.

Table 18 further discloses that the 73 kD polypeptide in fraction 4 comprises peptides 8, 10, 14, and 19, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 11, 12, 13, and 14, respectively, that the 80 kD polypeptide in fraction 4 comprises peptides 9, 18 and 11, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 1, 3, and 10; and that the 82 kD polypeptide in fraction 4 comprises peptides 4, 9, and 22, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 7, 8, and 9.

Moreover, Table 18 discloses that the 73 kD polypeptide in fractions 3 and fraction 4 when combined comprise peptides 10,12, 13, 8, 10, 14 and 19, whose amino acid sequence corresponds to the amino acid sequences set forth in SEQ ID NO: 1, 5, 6, 11, 12, 13, and 14; the 80 kD polypeptide comprises peptide 10, peptide 13, a 9 amino acid peptide, peptides 9, 18 and 11, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 1, 3, 4, and 10; and the 82kD polypeptide comprises peptides 12, 16, 4, 9, and 22, whose amino acid sequences correspond to the amino acid sequences set forth in SEQ ID NO: 1, 2, 7, 8, and 9.

Since the present claims are directed to compositions for treatment of psoriasis comprising a particulate antigen isolated from protozoa of genus *Leishmania*, wherein the antigen comprises polypeptides of fraction 3 and fraction 4 having apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kD., the literature search required for these new claims would impose no additional burden on the Examiner. Applicant respectfully requests that the Examiner withdraw the requirement.

Applicant earnestly solicits early and favorable action by the Examiner. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (973) 597-6170. The undersigned also may be contacted via e-mail at [blubit@lowenstein.com](mailto:blubit@lowenstein.com).